

**REMARKS**

Claims 1, 5-7, 10-12, and 15-26 currently appear in this application. The Office Action of April 21, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

**Claim Objections**

Claims 1 and 5-6 are objected to because in claim 1, line 17, the word "boyd" is an apparent typographical error.

The present amendment corrects this typographical error and replaces "boyd" with -body--.

**Double Patenting**

The double patenting rejection has been withdrawn.

**Art Rejections**

Claims 1, 5-7, 10-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5769796 to Palermo et al. in view of USP 4750953 to Tabei.

This rejection is respectfully traversed. The claims have now been amended to recite the specific hardness of each portion of the guide wire, namely, the high-rigidity

portion has a hardness of 350 (or 380) or more Hv, the low-rigidity tip end portion has a hardness of 250 (or 270) or less Hv, and the intermediate portion has a difference in hardness of 50 (or 30) or more Hv between the high-rigidity body portion and the low-rigidity tip end portion. None of the cited references even suggests this relationship among the body portion the tip end portion and the intermediate portion.

Support for the amendments to the claims and the newly submitted claims 18-26 can be found in the specification as filed as follows:

Claim 1: Figures 2 and 5, Sample No. 3 on page 30, paragraph [00118], Table 2, Sample No. 3, page 34, paragraph [00129] and Table 4.

Claim 18: page 34, paragraph [00129], Table 4, and Figure 2.

Claim 7: pages 42-43, paragraph [00151], Table 5, because the catheter of amended claim 7 comprises the same composition as that of the reinforcing metal member recited in claim 12.

Claim 19: pages 42-43, paragraph [00151], Table 5.

Claim 12: page 34, paragraph [00129], Table 4.

Claim 23: pages 42-43, paragraph [00151], Table 5.

Although Palermo teaches that it is conventional that a catheter guidewire be tapered along its length to allow

great flexibility in that remote region of the guidewire (column 1, lines 60-67; column 5, lines 20-27, Figure 1), and a guidewire having a body portion relatively high in rigidity and a distal portion (tapered portion) relative flexible (column 2, lines 16-30), there is nothing in Palermo et al. regarding a functionally graded Cu-Al-Mn alloy core wire for a guide wire, no functionally graded Cu-Al-Mn alloy catheter, and no functionally graded Cu-Al-Mn reinforcing metal member comprising a body portion having a high-rigidity body and a top end portion having a lower rigidity than that of the body portion.

In contrast to Palermo, the copper-based alloy wire of the present invention as claimed in amended claim 1 comprises a high-rigidity body portion having a hardness of 350 or more Hv, a low-rigidity tip end portion having a hardness of 250 or less Hv, and an intermediate portion having a difference in hardness of 50 or more Hv between the high-rigidity portion and the low-rigidity tip end portion, the intermediate portion having rigidity continuously or stepwise changing from the high-rigidity body portion to the low-rigidity tip end portion. The catheter of amended claim 7 comprises a high-rigidity body portion having a hardness of 380 Hv, a low-rigidity tip end portion having a hardness of 270 Hv, and an intermediate portion having a difference in

hardness of 30 Hv between the high-rigidity body portion and the low-rigidity tip end portion, the intermediate portion having rigidity continuously or stepwise changing from the high-rigidity body portion to the low-rigidity tip end portion. The reinforcing metal member of amended claim 12 comprises a high-rigidity body portion having a hardness of 380 Hv, a low-rigidity tip end portion having a hardness of 270 Hv, and an intermediate portion having a difference in hardness of 30 Hv between the high-rigidity body portion and the low-rigidity tip end portion, the intermediate portion having rigidity continuously or stepwise changing from the high-rigidity body portion to the low-rigidity tip end portion.

The characteristic features of each of the independent claims can be achieved by using a copper-based alloy comprising 3-10 weight % of Al and 5-20 weight % of Mn, the balance being substantially Cu and the inevitable impurities as a starting raw material. The copper-based alloy is formed into a desired shape such as a wire, a catheter, a reinforcing metal member, etc., maintained at a temperature of at least 500°C, and then rapidly quenched for hot working and cold working to transform the crystal structure thereof substantially to a  $\beta$ -phase. The resultant copper-based alloy is then subjected to an aging treatment comprising heating the

high-rigidity body portion at a temperature of 250-350°C, heating the tip end portion at a temperature continuously or stepwise changing from the heating temperature of the body portion to the heating tip end portion, as disclosed in paragraphs [0016]-[0020], and as recited in amended claims 1, 7 and 12 of the present application.

Tabei teaches the improvement in the shape memory characteristics of a copper-based shape-memory alloy, particularly, significantly improved resistance to intercrystalline cracking the grain boundary by the deposition of the fine grains of the Si-intermetallic compound and the improvement in the heat cycle characteristics thereof while maintaining the inherent good shape-memory properties (column 1, line 55 to column 2, line 9). However, Tabei is silent regarding the generation of the gradient properties in the shape memory, functionally graded Cu-Al-Mn alloy, particularly the improvement of the rigidity and the hardness of the shape memory alloy obtained by using an aging treatment as claimed herein, and formation of the functionally graded alloy by using a gradient temperature heater for allowing the shape memory copper ally to have the gradient properties.

Contrary to the Examiner's assertion that the heat treatment steps are irrelevant to the composition, obtained

thereby, the heat treatment and aging of the alloy produce different alloy structures. For example, Figure 3 is an optical photomicrograph showing the microstructure of the low-aging temperature portion of the functionally graded alloy of Sample 1, and Figure 4 is an optical photomicrograph showing the microstructure of the high-aging temperature portion of the functionally graded alloy of Sample 1. Figures 5 and 6 shows, respectively, the differences in hardness using different ageing temperatures or different aging times. These differences in hardness are now part of the claimed invention, and it is the heat treatment and aging of the alloy that produces the differences in hardness of the different parts of the guide wire.

Still further, Tabei is silent regarding a catheter comprising a metal pipe thereof and a catheter tube reinforced with the Cu alloy braid. Tabei merely teaches a wire with a diameter of 3 mm (column 2, line 65 to column 3, line 1), and there is no teaching of the mechanical properties of this wire. The copper alloy of Tabei differs greatly from the alloy of the present invention because Tabei contains an excess of 15-35 weight % zinc, thus greatly lowering the amount of copper in the alloy.

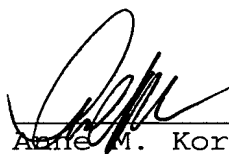
One skilled in the art reading Palermo et al. and Tabei would not achieve the guide wire of the present invention. Rather, one would achieve a guide wire made of a copper base shape-memory consisting essentially of 15-35% Zn, 3.2-10% Al, 0.01-1% Si, and at least one element selected from the group of 0.5-2% Ti, 0.01-1% Cr, 0.01-8% Mg, 0.01-2% Co and 2.1-4% Ni. While the guide wire so produced would be made of a shape memory alloy, there is no provision for achieving the different degrees of rigidity as in the present invention.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By



Anne M. Kornbau  
Registration No. 25,884

AMK:ma  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
G:\bn\t\taka\ishida8A\pto\Amendment-B.doc